


Application Number 	Application/Control No. 10/721,642	Applicant(s)/Patent under Reexamination FREY ET AL.	
	Examiner Javier G. Blanco	Art Unit 3738	



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			EXAMINER BLANCO, JAVIER G	
			ART UNIT	PAPER NUMBER
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			06/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/721,642

Applicant(s)

FREY ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/10/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 50-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-14, 50-52, 54-56, 58-68, and 70 is/are rejected.
- 7) ☒ Claim(s) 11, 53, 57 and 69 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Applicants' amendment of claims 1, 7-9, 54, 61, and 66 in the reply filed on April 10, 2007 is acknowledged.

Terminal Disclaimer

2. The terminal disclaimer filed on April 10, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 7,060,073 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 61 and 63-65 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Schaefer et al. (EP 0 916 323; cited in Applicants' IDS). For English translation, see US 6,143,032; having an effective filing date of November 12, 1998.

Referring to Figures 1-3 and 5, Schaefer et al. disclose a spinal implant comprising:

- (i) A leading end wall (7), the leading end wall may have an insertion tool-engaging portion (i.e., any “portion” of said end wall can be engaged by a tool);
- (ii) A trailing end wall (6), the trailing end wall may have an insertion tool-engaging portion (instrument receptacle 19);
- (iii) A concave posterior wall (5) extending between said leading end wall and said trailing end wall;
- (iv) A convex anterior wall (4) extending between said leading end wall and said trailing end wall;
- (v) An upper bearing member (upper face/surface) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall; and
- (vi) An opposite lower bearing member (lower face/surface) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall, wherein said posterior wall has a height that is less than (i.e., wedge-shaped or taper) a height of said anterior wall (see Figure 5; see column 4, lines 7-12), and wherein said trailing end wall and said leading end wall each have a height that is less than the height of both said anterior wall and said posterior wall. “A height” is broadly interpreted as any height along a wall.

Response to Arguments

5. With regards to the 102(a) rejection based on Schaefer et al. (EP 0 916 323; cited in Applicants’ IDS), Applicants’ arguments filed April 10, 2007 have been fully considered but they are not persuasive.

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a. With regards to claims 2 and 61, the Applicants argue that Schaefer et al. does not disclose “wherein said leading end wall and said trailing end wall each have a height that is less than the height of both said anterior wall and said posterior wall”. The Examiner respectfully disagrees. Figure 5 (see column 4, lines 7-12) clearly shows “a height” (e.g., the spacing between holes 10, 11) of either said leading end wall or said trailing end wall that is less than the height of both said anterior wall and said posterior wall. The claim language does not specify the extent of said “height” (e.g., from the upper bearing member to the lower bearing member). “A height” is broadly interpreted as any height along a wall.

6. Claims 1, 2, 4-10, 12, 13, 50-52, 61, 62, 65, and 66 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tropiano (US 5,607,424; cited in Applicants’ IDS).

Referring to Figures 1 and 2A, Tropiano discloses a spinal implant comprising:

- (i) A leading end wall (16), the leading end wall may have an insertion tool-engaging portion (i.e., any “portion” of said end wall can be engaged by a tool);
- (ii) A trailing end wall (18), the trailing end wall may have an insertion tool-engaging portion (threaded opening 39);
- (iii) A posterior wall (planar surface 22) extending between said leading end wall and said trailing end wall;
- (iv) An anterior wall (planar surface 20) extending between said leading end wall and said trailing end wall;
- (v) An upper bearing member (14) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall; and

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(vi) An opposite lower bearing member (12) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall, wherein said posterior wall 22 has a height that is less than (e.g., wedge-shaped or taper) a height of said anterior wall 20 (see Figure 1), and wherein said trailing end wall and said leading end wall each have a height that is less than the height of both said anterior wall and said posterior wall (see Figure 1). “A height” is broadly interpreted as any height along a wall. The terms “anterior”, “posterior”, “upper”, and “lower” are broadly interpreted as labels since the claim language does not indicate points of reference (e.g., upper bearing member faces the upper vertebra; anterior wall faces the anterior side of the spinal column; etc.). Said anterior wall 20 includes struts 50, anterior lateral openings 34, 38, and a middle opening 36. The upper and lower bearing members 14, 12 each include a cantilevered portion (see Figure 1 and Figure 2A) extending beyond said anterior wall (portions of 16, 18, and struts 50 extend outward and beyond planar surface 20).

Response to Arguments

7. With regards to the 102(b) rejection based on Tropiano (US 5,607,424; cited in Applicants’ IDS), Applicants’ arguments filed April 10, 2007 have been fully considered but they are not persuasive.

a. The Applicants argue: “*one having skilled in the art would recognize that “anterior”, “posterior”, “upper”, and “lower” are used to describe portions of the implant relative to anatomical features of the spinal column*”. The Examiner still maintains that the terms “anterior”, “posterior”, “upper”, and “lower” are broadly interpreted as labels since the claim language does not indicate points of reference (e.g., upper bearing member faces the upper

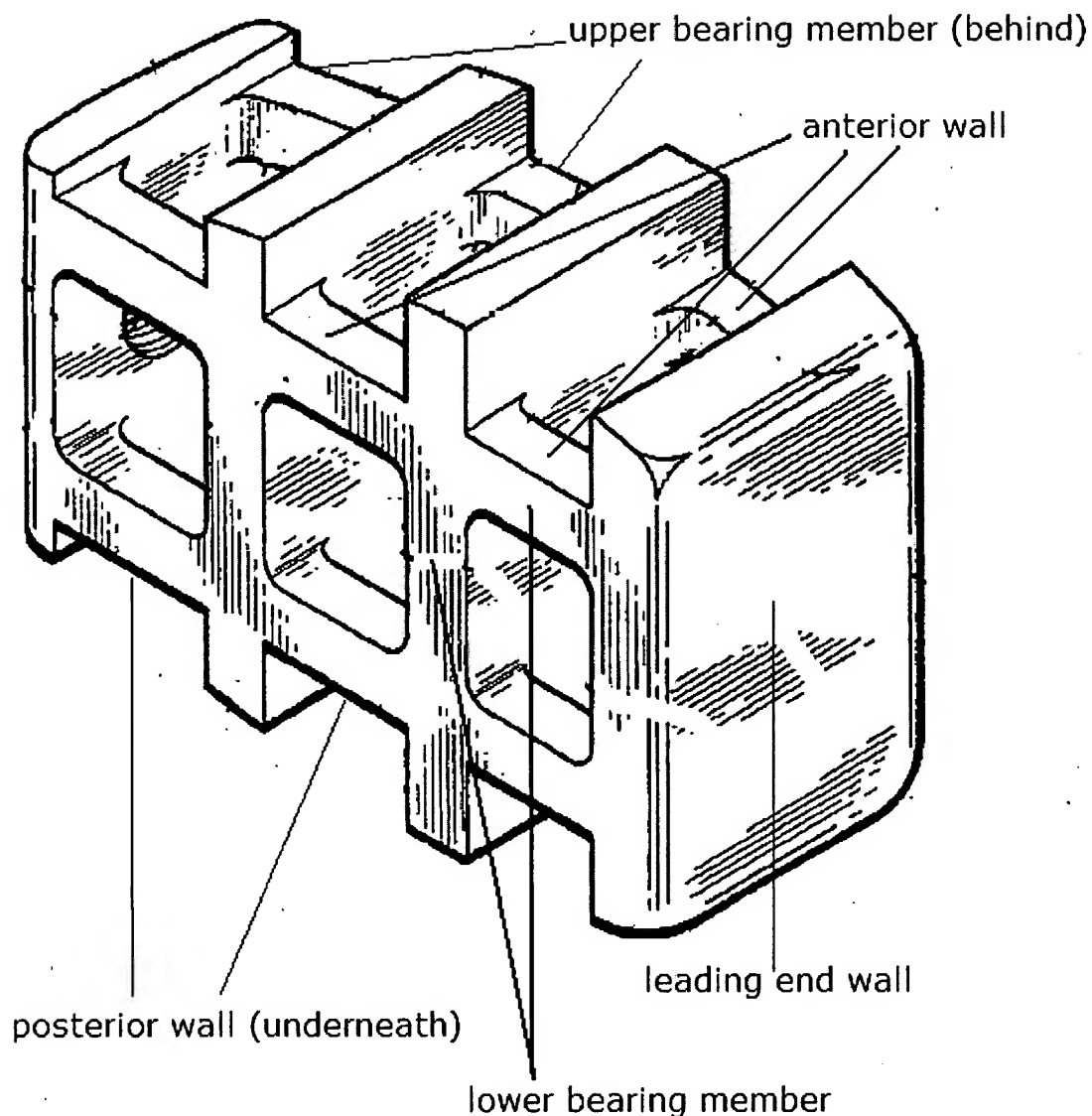
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vertebra; anterior wall faces the anterior side of the spinal column; etc.). It should be noted that it is the claims that define the claimed invention, and it is claims, not specifications that are anticipated or unpatentable. *Constant v. Advanced Micro-Devices Inc.* 7 USPQ2d 1064.

b. With regards to newly added limitation “*defining an implantation direction of the spinal implant*”, leading end wall 16 and trailing end wall 18 define a direction of implantation (see Figure 4).

c. With regards to “*wherein said posterior wall has a height that is less than the height of said anterior wall*”, the claim language does not specify the extent of said “height” (e.g., from the upper bearing member to the lower bearing member). “A height” is broadly interpreted as any height along a wall, and “a height” (e.g., the height of an opening 34, 36, or 38) of posterior wall 22 has a height that is less than “a height” (e.g., full extent of) of anterior wall 20 (which anterior wall 20 shares opening 34, 36, or 38 with posterior wall 22).

d. With regards to Applicants’ comment “the Office Action provides an inconsistent interpretation of Tropiano in rejecting the claims”, the previous indication of Figure 2A was just a typo. Figure 1 (shown below) clearly discloses the subject matter as claimed.



8. Claims 1, 2, 4-6, 8-10, 12-14, 50-52, 54-56, 58-62, 65-68, and 70 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cottle (WO 97/15248 A1). For English translation, see US 5,888,227 A.

Referring to Figures 2-8, Cottle discloses a spinal implant comprising:

- (i) A leading end wall (13), the leading end wall may have an insertion tool-engaging portion (i.e., any "portion" of said end wall can be engaged by a tool, or receptacle 19);

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(ii) A trailing end wall (14), the trailing end wall may have an insertion tool-engaging portion (i.e., any “portion” of said end wall can be engaged by a tool, or receptacle 19);

(iii) A posterior wall (15) extending between said leading end wall and said trailing end wall;

(iv) A curved/convex anterior wall (16) extending between said leading end wall and said trailing end wall;

(v) An upper bearing member (12) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall; and

(vi) An opposite lower bearing member (11) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall, wherein said posterior wall has a height that is less than (i.e., wedge-shaped or taper) a height of said anterior wall (see Figure 6), and wherein said trailing end wall and said leading end wall each have a height that is less than the height of both said anterior wall and said posterior wall. “A height” is broadly interpreted as any height along a wall. The anterior wall (16) comprises lateral openings 27, a middle opening 25/26, and lateral struts (each located between 27 and 28). The upper and lower bearing member further comprises an opening (24), and grooves (11) formed in surfaces thereof (see Figures). As shown in Figures 4, 5, and 8, the upper and/or lower bearing members may include at least one strut. As clearly shown in Figures 4 and 6, said upper bearing member and lower bearing member each include a cantilevered portion extending beyond said anterior wall.

Response to Arguments

9. With regards to the 102(b) rejection based on Cottle (WO 97/15248 A1), Applicants’ arguments filed April 10, 2007 have been fully considered but they are not persuasive.

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- a. The Applicants argue that Cottle does not disclose: “*defining an implantation direction of the spinal implant*”. The Examiner respectfully disagrees. Receptacles 16 are disclosed as capable of receiving an implantation/manipulation tool (see column 4, lines 23-26), and therefore define a direction of implantation. Regarding newly added limitation “*at least one strut extending between said posterior wall and said anterior wall*”, see Figures 4, 5, and 8 for at least one strut extending between posterior wall 15 and said anterior wall 16 (see, for example, the center strut running along the bearing member from anterior wall 16 to posterior wall 15).
- b. With regards to “*wherein said posterior wall has a height that is less than the height of said anterior wall*”, the claim language does not specify the extent of said “height” (e.g., from the upper bearing member to the lower bearing member). “A height” is broadly interpreted as any height along a wall. See Figure 6, wherein posterior wall 15 has a height that is less than a height of anterior wall 16.
- c. With regards to “*wherein said leading end wall and said trailing end wall each have a height that is less than the height of both said anterior wall and said posterior wall*”, the claim language does not specify the extent of said “height” (e.g., from the upper bearing member to the lower bearing member). “A height” is broadly interpreted as any height along a wall.
- d. With regards to claim 8 (i.e., cantilevered portion), Figures 4 and 6 show the extension of upper and lower bearing members 12, 11 beyond anterior wall 16 (and beyond posterior wall 15).
- e. With regards to claim 10, Figures 4-6 clearly shows the anterior wall (16) as comprising lateral openings 27, a middle opening 25/26, and lateral struts (each located between 27 and 28). The

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term “opening” is generally defined as: “an unobstructed or unoccupied space or place”; “a gap, hole, or aperture”.

10. Claims 1-7, 61, and 63-65 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Fuss et al. (WO 99/37255 A1; cited in Applicants’ IDS). See US 6,562,072 B1 for English translation.

Referring to Figures 1, 2A-2E, and 3E, Fuss et al. disclose a spinal implant comprising:

- (i) A leading end wall (lateral wall 9), the leading end wall having an insertion tool-engaging portion 5, and defining an implantation direction of the spinal implant;
- (ii) A trailing end wall (lateral wall 9), the trailing end wall having an insertion tool-engaging portion 5;
- (iii) A concave posterior wall (posterior face 11) extending between said leading end wall and said trailing end wall;
- (iv) A convex anterior wall (anterior face 10) extending between said leading end wall and said trailing end wall;
- (v) An upper bearing member (top cover face 6) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall; and
- (vi) An opposite lower bearing member (bottom cover face 6) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall, wherein said posterior wall has a height that is less than (i.e., wedge-shaped or taper) a height of said anterior wall (see Figure 1), and wherein said trailing end wall and said leading end wall each have a height that is less than the height of both said anterior wall and said posterior wall.

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“A height” is broadly interpreted as any height along a wall. The anterior wall (anterior face 10) comprises lateral openings 12, a middle opening 12, and first/second lateral struts (each located between openings 12). The upper and lower bearing member further comprises openings 7, grooves 14 formed in surfaces thereof, and struts 8.

11. Claims 8, 9, 12, 14, 54, 55, 58, 60-62, and 65-67 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Camino et al. (US 6,086,613 A).

Referring to Figures 1-30, Camino et al. disclose a spinal implant, which implant can be implanted using a variety of surgical techniques (e.g., lateral approach, anterior approach, antero-lateral approach, etc.; see column 6, lines 2-9) and may include a cylindrical shaped outline (e.g., Figures 1-7), an oval shaped outline (e.g., Figures 8-10), or a crescent shaped outline (e.g., Figures 27-30), said spinal implant comprising:

- (i) A leading end wall (lateral wall of spacer 12), the leading end wall defining an implantation direction of the spinal implant;
- (ii) A trailing end wall (lateral wall of spacer 12), opposite said leading end wall;
- (iii) A posterior wall (a posterior-facing wall of spacer 12) extending between said leading end wall and said trailing end wall;
- (iv) An anterior wall (an anterior-facing wall of spacer 12) extending between said leading end wall and said trailing end wall;
- (v) An upper bearing member (top end cap 10) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall; and

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(vi) An opposite lower bearing member (bottom end cap 10) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall, wherein said posterior wall has a height that is less than (i.e., wedge-shaped or taper) a height of said anterior wall (see Figure 1), and wherein said trailing end wall and said leading end wall each have a height that is less than the height of both said anterior wall and said posterior wall. Since the claim language does not specify the extent of said “height” (e.g., from the upper bearing member to the lower bearing member), then “a height” is broadly interpreted as any height along a wall. The anterior wall comprises lateral openings 44, a middle opening 44 (defined between first and second struts), and struts 42. The upper and lower bearing member further comprises openings and grooves formed in surfaces thereof. The upper and lower bearing members each include a cantilevered portion (e.g., projections 78; outer lip 282; among others) extending beyond said anterior wall (see Figures). The anterior wall and the posterior wall are positioned on opposite sides of a center axis.

12. Claims 1, 2, 4, 5-7, 61, and 65 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Grosse et al. (WO 97/23175 A1).

Referring to Figures 1-6, Grosse et al. disclose a spinal implant comprising:

- (i) A leading end wall (lateral wall), the leading end wall having an insertion tool-engaging portion 10/11, and defining an implantation direction of the spinal implant (Figures 4 and 5);
- (ii) A trailing end wall (lateral wall), opposite said leading end wall, the trailing end wall having an insertion tool-engaging portion;

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(iii) A posterior wall (posterior face 2a) extending between said leading end wall and said trailing end wall;

(iv) An anterior wall (anterior face 2b) extending between said leading end wall and said trailing end wall;

(v) An upper bearing member (top face) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall; and

(vi) An opposite lower bearing member (bottom face) extending between and connected to said leading end wall, said anterior wall, said posterior wall, and said trailing end wall, wherein said posterior wall has a height that is less than (i.e., wedge-shaped or taper) a height of said anterior wall (see Figure 5), and wherein said trailing end wall and said leading end wall each have a height that is less than the height of both said anterior wall and said posterior wall. Since the claim language does not specify the extent of said “height” (e.g., from the upper bearing member to the lower bearing member), then “a height” is broadly interpreted as any height along a wall. The upper and lower bearing member further comprises struts 6A extending between the posterior wall and the anterior wall, and apertures 3 or apertures 6. The anterior wall and the posterior wall are positioned on opposite sides of a center axis.

Allowable Subject Matter

13. Claims 11, 53, 57, and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

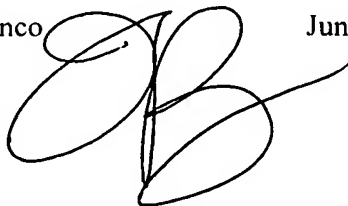
14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco



June 13, 2007



David H. Willse
Primary Examiner